at this point. Do you want to break at this point or should we proceed because of time constraints, the weather and all? Maybe we should proceed.

Okay. I think we'll just go ahead and skip the break, and if people need to -- yeah. Well, that's supposed to speed things up if everybody needs to leave.

Okay. Bob Doyle has a brief announcement while Alicia is gone.

MR. DOYLE: If anyone needs a cab, sign up at the registration desk outside, you know, when you feel you have a minute to get a cab if you need one to leave here.

If you didn't hear that, Dr. Phillips indicated that if you're going to National Airport, considering the weather, you're better off going by the subway. That would mean when you get the cab, you want to take it over to the Shady Grove station and take the Red Line down.

CHAIRMAN GARRA: The next phase here is to ask if there's any public comment. At this point, this is the second of two sections where the public is allowed to speak.

Are there any of the public who would like to address the panel?

(No response.)

CHAIRMAN GARRA: I see no takers on that.

MR. DOYLE: Or none of the speakers that were missing from this morning, or one? Apparently not.

CHAIRMAN GARRA: Okay. So at this point then, before we move to the panel recommendations and vote, is there anything additionally that the FDA would like to address?

MR. SEGERSON: I think we're fine. We appreciate the discussion, and we're looking forward to your recommendations.

CHAIRMAN GARRA: Finally, is there any last comments the sponsor would like to make at this point?

MR. DOYLE: Your last chance.

CHAIRMAN GARRA: This is your last chance.

(No response.)

CHAIRMAN GARRA: Okay. So --

MR. DOYLE: Dr. Phillips gave me one other little tidbit concerning transportation, that it's perfectly clear outside there's no snow accumulation and no snow on the ground. So it looks like things should at least in this area --

(Laughter.)

MR. DOYLE: I know not everyone is from this area, but in this area, you should be able to get around fine.

CHAIRMAN GARRA: You could still take the subway though if you don't like light.

Okay. So at this point then we're going to move to the panel recommendations regarding PMA P000041.

The medical device amendments to the Federal Food, Drug, and Cosmetic Act, as amended by the Safe Medical Devices Act of 1990, allows the Food and Drug Administration to obtain a recommendation from an expert advisory panel on designated medical device pre-market approval applications, PMAs, that are filed with the agency. The PMA must stand on its own merits, and your recommendation must be supported by safety and effectiveness data in the application or by applicable publicly available information.

Safety is defined in the act as reasonable assurance based on valid scientific evidence that the probable benefits to health under conditions of intended use outweigh any probably risks.

Effectiveness is defined as reasonable assurance that in a significant proportion of the population the use of the device for its intended uses

and conditions of use when labeled will provide clinically significant results.

Your options for recommendation and vote are as follows. It's approvable if there are no conditions attached. It can be approvable with conditions. In this situation the panel may recommend that the PMA be found approvable subject to specified conditions, such as physician or patient education, labeling changes, or further analysis of existing data.

Prior to voting, all of the conditions should be discussed by the panel and written down also.

Finally, it can be not approvable. The panel may recommend that the PMA is not approvable if the data do not provide a reasonable assurance that the device is save or if a reasonable assurance has not been given that the device is effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling.

If the vote is for not approvable, the panel should indicate what steps the sponsor may take to make the device approvable.

Okay. At this point, I'm supposed to have someone make a motion. This could be sort of a

complicated step. Normally the lead discussant gets to initially propose the motion that gets hacked over by the rest of the panel.

So I'll let Dr. Toledano make a motion.

DR. TOLEDANO: I forgot about that part.

CHAIRMAN GARRA: I would have told you at the break, but we didn't have one.

DR. TOLEDANO: Oh, okay. I'm trying to remember how this goes, and so just as a point of clarification, I think if we move to approve with conditions, we do that motion and then we discuss each condition. That is correct. Oh, good.

I will make a motion to approve with conditions.

CHAIRMAN GARRA: Is there --

DR. BERG: I'll second it.

CHAIRMAN GARRA: Okay. We have a second to that.

Let's have a little discussion now on the conditions under which -- so we're approving it with conditions, and then approving it with conditions again. Is that what you're saying?

Okay. So I'll have, first of all, a vote by the panel whether we should approve this with conditions to be specified, and then we'll go back

after we get the conditions and approve it again. Okay?

Those in favor, raise your hands.

(Show of hands.)

CHAIRMAN GARRA: Those opposed.

(No response.)

MR. SEGERSON: Excuse me. Would you announce the vote, please?

CHAIRMAN GARRA: The vote was five in favor, none against.

Okay. So now that we've decided to approve it with conditions, we have to decide on what conditions, and I would like, rather than -- okay. I think what we'll do is we'll just go around and let each member propose conditions, and then if it gets to you and they're already covered, then you don't need to do anything.

So, Wendie, do you want to start?

DR. BERG: I would like to propose that there be conditions on the labeling to include restricting this, at least state that it was validated in patients who are men who have a smoking history, and that it has not been validated for use in women or in non-smokers.

I'm not sure about the exact language,

but --

CHAIRMAN GARRA: Okay. Any discussion or revisions to that?

DR. TOLEDANO: I think also the ages. Oh, I'm sorry.

CHAIRMAN GARRA: That's okay. Anybody can chime in here.

Dr. Mehta.

DR. MEHTA: Minesh Mehta here.

I'd just like to expand that a little. I think we should be specific about the population in which it should be used, given the fact that it was tested on a very limited population. My suggestion would be it should be male adult smokers with a high risk of suspicion for cancer, and then if date are provided for other populations, the label can be expanded.

DR. TOLEDANO: So this is Toledano.

And I just wanted to say as far as that adult goes, I think the 45 year cutoff should be explicitly stated in terms of the validation.

CHAIRMAN GARRA: And should we state that the films need to be 20 years old, as well?

DR. TOLEDANO: No.

(Laughter.)

DR. BERG: We'll let them slide on that one.

CHAIRMAN GARRA: We want to be certain about this now.

DR. MEHTA: That doesn't affect the biology. So I think we can live with it.

CHAIRMAN GARRA: Okay.

DR. MEHTA: The other factors affect the biology.

CHAIRMAN GARRA: Okay.

DR. SMITH: John Smith here.

And I think along those lines we have to be pretty clear, and I think it's in the labeling somewhere at this point, but may be more prominently featured what the actual benefit was in the study so that people k now what they're getting.

CHAIRMAN GARRA: Dr. Smith, we are at the point where we might have to specify what we think that might be. Do you have a -- how would you like to phrase that?

DR. SMITH: It's difficult. I mean, I'm not a statistician, and just by the fact that if you looked at some of what I gleaned from this morning, the fact that it looked like approximately half of the regions of interest did not actually include the

lesions that ended up being identified by follow-up studies.

I don't know about the terminology "limited."

CHAIRMAN GARRA: Did you want something on the statement of the magnitude of the benefit or the fact that -- further amplification on the fact that readers were identifying areas that were not the cancer, but still ended up finding a cancer?

DR. SMITH: Yeah, or maybe I want both lines. I think that, you know, you're looking at just to pick some of the numbers that I saw and the benefits around the eight percent increase in sensitivity range, but then it's lower than that.

It's hard for me to be more specific because I think the numbers are a little ambiguous. It looks like it had some benefit, but I think the message that we have to send in the labeling is that every region of interest does not convey that there is a cancer there, and I think it would be unwise to send it out there with labeling that suggested that every time a region of interest is drawn that there is definitely an abnormality in that area.

DR. TOLEDANO: I'd like to pick up on that point, if I may.

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DR. TOLEDANO: I'd like to pick up on that point, if I may.

CHAIRMAN GARRA: Yes, please.

DR. TOLEDANO: Dr. Toledano.

I also felt that there could be more explicit mention of the types of false positive ROIs and the occasions where they might be missing in the warnings and precautions of both the labeling and the user's manual, and specific suggestions would include to state that ROIs may be present that are just marking anatomical structures and things like that, just to make it clear what's happening and also more on the warnings and precautions, that if the radiologist interprets the film and sees a possible lesion and that lesion is not marked by the device, that does not mean that the lesion is not a cancer. It just means that the device didn't pick it up,a nd people should really be using this as a CAD tool.

And I know that that is emphasized to a point. I just wonder how much stronger and how much more explicit it could be made.

CHAIRMAN GARRA: Dr. Harms.

DR. HARMS: Steve Harms.

I think we're extrapolating a lot into this data as though it was a -- we're thinking about this as a randomized, prospective, clinical trial as we're used to reviewing, and we have entrance

DR. HARMS: I would go along with stating that what the trial said, but not in restricting its use.

CHAIRMAN GARRA: Yeah, and I think the only thing that Dr. Berg wanted was an explicit statement somewhere in the labeling that the trial did not include certain groups: women, children, that sort of thing.

DR. BERG: Dr. Wendie Berg.

I just -- yeah, exactly. I wanted to not only make it clear what was done to validate or where this machine has been validated, but I also think it should be very explicitly stated, the level of sensitivity that was achieved with this machine because I think it gives the user a lot better sense to know that 66 percent of cancers ranging from nine to 30 millimeters in size were detected by this machine, depicted by this machine. That is a very useful number.

CHAIRMAN GARRA: Instead of just having the change in sensitivity that a user could expect, you want to see what the machine --

DR. BERG: I want it very explicitly spelled out what has been achieved. It could be done in a few sentences, but I think it gives a much better

perspective when you're going to start using this that, okay, half or so of the cancers that I'm interested in may not be seen by this machine.

CHAIRMAN GARRA: Dr. Mehta.

DR. MEHTA: Just a clarification question. Doesn't the label have two components? One is a component that says this is what it's approved for, and then a second component that says a warning. So the issue about the radiologist picking up a cancer and then relying on the machine to say this is not a cancer, maybe that should go in the warning component saying when this is done disastrous results can occur because that's potentially what would have happened to those patients. The cancers would have been missed.

CHAIRMAN GARRA: Is there a warning section?

DR. BERG: There is.

PARTICIPANTS: Yes.

DR. MEHTA: The reason I state that is because on the document dated January 18th, 2001, page 2, the sponsor was asked the specific question: does the device provide diagnostic information on which treatment or therapy is based such that if misapplied, it could result in serious injury or death? And the response was no.

I think that's not correct. If it's misapplied, it can result in serious injury or death because it can miss a cancer.

CHAIRMAN GARRA: Yeah, they state it in sort of in the warnings, in their labeling section. In their PMA they state that the device will miss some little nodules, and the user should not be dissuaded from working up a finding if the device fails to mark that site. That's fairly explicit. We could put it in bold letters or something.

I think the FDA sort of understands what we mean by that.

DR. MEHTA: Well, again, to go back to the drug scenario, often what's done in these warnings is people are told if you do this with this drug, expect this problem, and I think that's how specific the warning needs to be, saying if you rely on this to read your chest X-rays as opposed to the radiologist doing the chest X-ray, this is what can happen. You can miss a cancer.

You know, the warning has to be not just a very general warning people think it's just a feel good kind of thing, but a real life scenario, which is what happened in this study. Cancers were missed when radiologists changed their mind.

CHAIRMAN GARRA: How about -- I think we could couple Wendie's suggestion of giving the percentage for sensitivity, saying it's 66 percent accurate. So do not use this to change your initial interpretation unless it's to add nodules. Otherwise you will miss cancers, something like that.

Any other comments?

DR. BERG: I have one comment which actually relates to experience with what's happened with mammography with the R-2 technologies, and that is should there be anywhere in here that this is intended only to be used in conjunction with the radiologist's interpretation of the X-ray more explicitly. Because what's happened there is people are advertising on the Web that they'll read your mammogram and put it through an R-2 and send you the printout, and then you have to go back to the radiologist and talk to him about it.

And I certainly don't want to see that happening with chest X-rays. So is there anything we can do to preclude that possibility?

CHAIRMAN GARRA: That would just be a modification on the indications, right? Use as an adjunct?

DR. TOLEDANO: I believe it's explicit in

the indications.

DR. SACKS: It's pretty explicit in there now.

This is Bill Sacks.

I would just say we did put that in the labeling. That has limited effectiveness, but our Office of Compliance gets called in when such a thing happens.

CHAIRMAN GARRA: Yeah, it says the device is intended for use an aid only after the physician has performed an initial interpretation of the radiograph.

DR. SACKS: It's right in the indication, yeah.

DR. BERG: But that doesn't preclude somebody advertising that they'll send it through and spit out a printout. It says after. It doesn't say at the time of. I don't know.

CHAIRMAN GARRA: I don't think --

DR. BERG: I'll let you guy wrestle with that. I just throw that out there for discussion.

CHAIRMAN GARRA: That's for the malpractice lawyer, what you're doing.

(Laughter.)

CHAIRMAN GARRA: I don't think they can do

that. I think that they don't regulate the practice of medicine. They can only regulate the label, and if people choose to ignore it, there's only so much you can do.

Okay. So let me try to state the various -- you weren't writing these down, were you?

MR. DOYLE: I was.

CHAIRMAN GARRA: Bob Doyle has written them down, and we will listen to them, make slight modifications and decide whether we can vote on these modifications.

MR. DOYLE: There were a lot of things thrown out there, but I boiled down to five conditions, and, again, subject to continuous rewording. In fact, this first one was debated. So I'll just put it down as it came across.

First, the device should be used for male adult smokers over 45 years old with high risk of cancer.

Dr. Harms seemed to have a --

CHAIRMAN GARRA: That's not -- go ahead.

DR. HARMS: I think I would reword that perhaps to say the device was tested in a group of male smokers.

DR. BERG: I would change the word

"tested" to "validated."

DR. HARMS: "Validated," yeah. That's probably better.

DR. SMITH: John Smith.

Just, I guess, the attorney in me. Using "should" is a very dangerous thing. You're almost implying a standard of care. Validation, much more acceptable.

MR. DOYLE: The device was validated with adult smokers over 45 years old with a high risk of cancer.

DR. BERG: Adult male.

MR. DOYLE: Yeah, adult.

CHAIRMAN GARRA: Dr. Segerson.

MR. SEGERSON: I just wanted to recap briefly the way we're doing the labeling these days. The condensed version of the labeling that we approve is we're tentatively calling essential prescribing information. That now includes a section describing the clinical data on which it's based, and that section would include a thorough description of the target population used to develop this data.

And then that's separate from the indication for use, which doesn't necessarily have to coincide, and as you saw, right now we tentatively

have a different -- I mean suggested indications for use, and of course we have your comments on that as well.

And also, of course, as somebody already said, we have warnings. We have contraindications. We have precautions, a lot of other sections in that essential prescribing information.

CHAIRMAN GARRA: I think the intent here of the panel is to make sure it's prominently displayed near the front because we figure that people won't read more than two paragraphs into it.

DR. BERG: Exactly.

CHAIRMAN GARRA: Unfortunately.

MR. SEGERSON: Okay.

CHAIRMAN GARRA: But you're right.

MR. DOYLE: I'll read this first condition once more, and then maybe you can vote on this if it's close.

The device was -- so we're going to have a condition that we'll indicate in the labeling -- the device was validated with adult male smokers over 45 years old with a high risk of cancer.

They should vote on that.

CHAIRMAN GARRA: Okay. Those in favor of that condition being placed, raise your hands.

(Show of hands.)

MR. DOYLE: Four and one abstention. Do you want to say that?

CHAIRMAN GARRA: There are four yeses and one abstention, no noes.

Okay. Let's move on to the next one.

MR. DOYLE: Oh, sorry. This one was also labeling. Labeling will identify the degree of benefit that can be expected from the device.

CHAIRMAN GARRA: I think there, yeah, we mean to be that we would like it to be as specific as possible regarding overall performance, sensitivity, and change in sensitivity that can be expected.

MR. DOYLE: Do you want to take a vote on that?

CHAIRMAN GARRA: Okay. Those in favor of that condition being placed raise your hands.

(Show of hands.)

CHAIRMAN GARRA: Those opposed?

(No response.)

CHAIRMAN GARRA: Dr. Mehta is going to be upset. He's missing all of these votes.

MR. DOYLE: Do you want to announce that vote?

CHAIRMAN GARRA: The vote was four in

favor, one abstention, no negatives.

MR. DOYLE: The third one I have is more explicit description of the ROIs that the device is likely to mark, to alert users that the device will generate substantial numbers of false positives.

DR. TOLEDANO: What about the false negatives?

MR. DOYLE: Do you want to add "and false negatives"?

DR. TOLEDANO: Yeah, because I think that's the whole point, is like that if the radiologist sees something and the device doesn't mark it, we don't want them to change their answer. We want them to keep it.

MR. DOYLE: All right. I added in false negatives.

CHAIRMAN GARRA: Now, the question here is that sort of dovetails into the one that we were going to put in the warnings.

DR. TOLEDANO: Well, the warnings are part of the labeling.

CHAIRMAN GARRA: Right, but the warning section was also going to carry something about the sensitivity, machine sensitivity alone.

DR. TOLEDANO: Oh, right, okay.

MR. DOYLE: We'll work it in.

CHAIRMAN GARRA: Okay. Those in favor of that condition being place.

DR. TOLEDANO: I'd like to read it again.

CHAIRMAN GARRA: Yeah, read it one more time.

MR. DOYLE: Dr. Mehta didn't hear it.

A more explicit description of the ROIs that the device is likely to mark to alert users that the device will generate substantial numbers of false positives and false negatives.

CHAIRMAN GARRA: Those in favor, raise your hands.

(Show of hands.)

CHAIRMAN GARRA: We have five in favor, no negatives.

MR. DOYLE: The next one I have is state explicitly the specifics of what the device has shown to achieve.

Some of these seem to overlap, but that was the next one. That was based on Dr. Berg's statement explicitly.

CHAIRMAN GARRA: Have we already covered that, do you think? Is there something else, Wendie, that you --

DR. BERG: I guess the issue is have we really established that they're going to include the exact sensitivity of the device.

CHAIRMAN GARRA: I want to say that.

DR. BERG: I want to see that in there.

CHAIRMAN GARRA: Yeah.

MR. DOYLE: State the exact sensitivity?

DR. BERG: I mean the number I had from the presentations and from the PMA was 66 percent sensitivity has been demonstrated for cancers nine to 30 millimeters in size. I mean, I think that number, if I were going to use this, I'd want to know that number right up front.

CHAIRMAN GARRA: So I would couple that in with the statement on the change.

MR. DOYLE: Well, we can have all of these conditions. There's no harm in having some extra conditions.

So state explicitly the specifics of what the device has been shown to achieve, and specifically the sensitivity shown for the device.

CHAIRMAN GARRA: Okay. All those in favor of that condition being placed?

(Show of hands.)

CHAIRMAN GARRA: Five in favor.

MR. DOYLE: And the last one I have written down: add a warning that indicates what can potentially happen if a cancer is missed.

CHAIRMAN GARRA: I think -- is that what -- I think we wanted to state that slightly differently than that, didn't we, Dr. Mehta?

DR. MEHTA: Yeah, I think that might be a bit too general. I think what we might want to state is that the primary interpretation should be the radiologist's interpretation,a nd a negative result on the CAD assisted reading should not construe sufficient reason to alter the diagnosis.

Because this could lead to a missed cancer.

DR. BERG: They say that already. It says the device will miss some lung nodules and user should not be dissuaded from working at the finding if the device fails to mark that site. Do you want something different from that?

DR. MEHTA: Well, I think the specific issue is, one, the radiologist picks it up, and then going back --

MR. SEGERSON: The transcriber didn't hear your comment, Dr. Berg.

DR. BERG: Oh, I said the comment is

already in the labeling section in their PMA, which says the device will miss some lung nodules, and a user should not be dissuaded from working up a finding if the device fails to mark that site.

I just want clarification of what do we want it to say different from that.

DR. MEHTA: So it sounds like that's covered.

CHAIRMAN GARRA: I would just add maybe a sentence to that. I would just add in that sentence I think you wanted some emphasis to that sentence --

DR. MEHTA: Exactly.

CHAIRMAN GARRA: -- which is a little vague, and I would say if this procedure is not followed, cancers will be missed using this device.

DR. MEHTA: I agree. I feel there has to be some urgency in that statement because we don't want some radiologist who thinks this is the most sophisticated computer device out there to say, "Well, this is a computer. Obviously it knows better than I do."

CHAIRMAN GARRA: So you can just append that sentence to the existing one. If this procedure is not followed, cancers will be missed using this device.

MR. DOYLE: Okay.

CHAIRMAN GARRA: That's in the warning section.

MR. DOYLE: If the procedure and warnings are not followed, potential cancers may be missed, right?

CHAIRMAN GARRA: Yeah, but I think we want to couple it to that specific one because they're going to think that's a general statement.

DR. MEHTA: Which one is that?

CHAIRMAN GARRA: Well, it doesn't have a number. It's bullet three, sub-bullet one.

You ought to number these things, you guys.

PARTICIPANT: We'll take that under advisement.

MR. DOYLE: All right. Based on that bullet, sub-bullet two, bullet three, sub-bullet two --

CHAIRMAN GARRA: Sub-bullet one.

MR. DOYLE: Sub-bullet number one, if this procedure is not followed, there's a potential that cancers may be missed.

CHAIRMAN GARRA: Is that strong enough, "potential that cancers may be missed"?

Okay. Those in favor of this condition being placed?

(Show of hands.)

CHAIRMAN GARRA: Five in favor, no opposed.

MR. DOYLE: That's all I have. Are there any others?

CHAIRMAN GARRA: Okay. Are there any other conditions that the panel feels are necessary?

(No response.)

CHAIRMAN GARRA: Okay. Seeing no further conditions, we will now proceed to a vote on the whole PMA. Those in favor of approving this PMA with the conditions we have just mentioned, I'd like you to raise your hands.

Before we do that, does anybody wish to have all of the conditions read to them again?

(No response.)

CHAIRMAN GARRA: Nobody seems to want to.

Okay. Those in favor or approval with conditions under the conditions we have just discussed and approved, raise your hands.

(Show of hands.)

CHAIRMAN GARRA: Five in favor. No opposed.

Okay. At this point, I'm not going to read all of those conditions again. That's what the script tells me to do.

What we have to do at this point though, I'd like each of -- I would like to go around the panel and have each member briefly state the reasons for deciding to approve this PMA with the conditions as outlined.

So we can start with you, John.

DR. SMITH: I think it's a useful device as long as the end user, that is, the radiologist, understands what the product actually has been demonstrated to do.

CHAIRMAN GARRA: Dr. Mehta.

DR. MEHTA: I felt that the device should be approved because unlike most of the people who voted on this, I wear a different hat. My primary mission, clinical mission in life is I treat patients with lung cancer, and as a consequence, I see a whole host of people die of this disease, and I believe even the small number of lives that we can save by early detection is a huge step forwards.

The reason I felt conditions were necessary is because I felt that the sponsors had a very limited data set on which they showed the

efficacy, and it would be very nice to see this broadened in the future to a much bigger population base.

CHAIRMAN GARRA: Thank you.

Dr. Harms.

DR. HARMS: I agree. This is a substantial disease. This device, I believe, is the beginning of a new age of early detection where we may have a substantial benefit, and I believe the risk is minimal.

CHAIRMAN GARRA: Dr. Berg.

DR. BERG: I would like to congratulate the sponsor on a well prepared PMA. I thought it was very nicely done. I thought the statistical considerations, the trial was conducted very well.

I am concerned that this is a very marginal benefit relative to CT, and I still have reservations in that regard in clinical practice, but I think that you deserve every consideration to go forward with this, and this is certainly one step in a process that's quite complex.

CHAIRMAN GARRA: Dr. Toledano -- I'm sorry. What? Oh, Marilyn. Marilyn Peters.

MS. PETERS: Although I'm not a voting member, I think that anything that will help in the

early detection of any kind of cancer, and we're talking lung cancer here, is a benefit for the population.

DR. TOLEDANO: This is Dr. Toledano. Oh, no. Dr. Segerson go first?

No. Okay. So it's just me, Dr. Toledano, and I can't say any better what my colleagues have already said.

CHAIRMAN GARRA: And I get to wrap it up. I'm happy that we approved this device. The data set was limited, and we had to place some conditions based on that, but I think it's a start. With the coming age of computer aided radiography, it's the start of a lot of advances in computer aided detection and diagnosis, and I think we're all happy and proud to be present at the early stages of it.

I would also like to thank the FDA for what I consider yeoman work on doing statistical analysis with this data set. It was a data set that lent itself to careful analyses every which way, and they did that.

And some of the points that were brought out were, I think, kind of subtle ones, and I think we all learned a lot about how to evaluate these types of imaging studies from the lessons we learned today.

Thank you very much.

MR. DOYLE: I have a few.

CHAIRMAN GARRA: Yeah. Bob Doyle has a few comments.

David Segerson first.

MR. SEGERSON: Well, I'm not quite sure how the procedure goes at this point, but I don't want to miss an opportunity to thank the panel. You've all worked very hard, and I enjoyed your deliberations, and you came out in spite of the threatening weather that didn't quite materialize here anyhow.

But, again, on behalf of FDA, thank you very much.

CHAIRMAN GARRA: Bob Doyle has a few comments to make, and then I'll close the meeting.

MR. DOYLE: Before we adjourn for the day, I would like to remind panel members that they are required to return all of the materials they were sent pertaining to the PMA itself. Of course, materials that was presented at the meeting itself, like the slides and so forth, if you're interested in keeping those, you certainly can because that is all now public information.

Anything you want to leave behind, you can just leave at your table, and we'll have it picked up.

If there's any material you left at home, you can send it to me.

And this comment is for the general audience here. Please pick up around your chairs cups and anything else that you might have brought into this meeting. Please, there's barrels outside the room here that you can put any materials like that.

And, again, I'll add my thanks. I know people came from a long distance, and as I was telling people earlier this morning, I certainly never watched the Weather Channel as much this week as I ever did before.

(Laughter.)

MR. DOYLE: And I had an awful lot of phone calls on my machine yesterday about this meeting, but we did get a quorum, and we had the five members we needed here, and I really appreciate it because I know it was an effort for many of you to get here, and really the FDA appreciates it as well.

CHAIRMAN GARRA: Okay. I'd like to finally thank each of you as members of the panel for coming. I thought we had a great discussion today, and we sort of worked as a team and hacked out what we wanted to do here, and it was led by a very capable person, Alicia Toledano, and I would like to thank her

because she'll need these thanks to tide her over if she's stranded here tonight, which is very likely.

So let's give a round of applause.

(Applause.)

CHAIRMAN GARRA: And did you want to say something?

DR. FREEDMAN: On behalf of Deus Technologies, I'd very much like to thank the panel and the FDA for all of their work in this effort. We are delighted to have received approval, and I want to read the exact language of the conditions, but I consider them appropriate.

Thank you.

CHAIRMAN GARRA: Thank you for coming and making the presentation.

I don't think we have any further business today. So we are adjourned.

(Whereupon, at 3:39 p.m., the meeting in the above-entitled matter was concluded.)

CERTIFICATE

This is to certify that the foregoing transcript

in the matter of: RADIOLOGICAL DEVICES
PANEL MEETING

Before: FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND
RADIOLOGICAL HEALTH

Date: MARCH 5, 2001

Place: ROCKVILLE, MARYLAND

represents the full and complete proceedings of the aforementioned matter, as reported and reduced to typewriting.

Rebecca Davis